

### Remarks

The following is a response to Office Action dated November 1, 2005.

In response to the 35 U.S.C. 112, second paragraph rejection, claim 24 has been amended to state that it is the needle assembly that is connected to the medical device.

A substitute Abstract is being submitted in response to the objection to the length of the original Abstract.

Claims 1-3, 7, 20-22 and 26 were rejected under 35 U.S.C. 102(b) as being anticipated by Gyure (US 5,681,295). Claims 4-10, 23-27 and 28, which depend respectively from independent claims 1 and 20, were rejected under Gyure '295 in combination with a number of secondary references, namely, Landis (US 5,490,841), Gyure (US 5,669,889) and Crawford (2002/0161336). In addition, claims 11-13 and 16-17, as well as claims 5 and 24, were rejected under 35 U.S.C. 103 as being obvious over Gyure '295 in combination with Johnson et al. (2002/0010433). Claims 14 and 18-19 were rejected under the combination of Gyure '295 and Johnson in combination with the above-noted secondary references. Moreover, all of the claims were rejected under the obviousness-type double patenting rejection in view of claims 1, 2, 5, 9, 10, 17, 23 and 24 of co-pending application No. 10/649,837.

To respond to the obviousness-type double patent rejection, submitted with this amendment is a Terminal Disclaimer for obviating the provisional double patenting rejection.

Applicants hereby traverse the prior art rejections as follows.

The instant invention is directed to the novel concept of connecting the needle sheath that is used to protect the needle prior to its use directly to a collar that is rotatably mounted to a needle hub. This is shown clearly in Figs. 3 and the cross-sectional cut-away

views of Figs. 4 and 5. In particular, as shown in Figs. 4 and 5, needle sheath 12 is removably coupled to collar 6 by the interaction of rib 68 at collar 6 and groove 90 at sheath 12. As further shown in Figs. 4 and 5, sheath 12 has no interaction with needle hub 4, and more specifically extension 24 of needle hub 4. That the sheath covering the needle is connected to the collar, and not to the needle hub, is believed to be more clearly set forth in amended claims 1 and 20.

In contrast, Gyure '295 shows, and specifically discloses, that its collar 44 (Fig. 2) is fitted to the collar receiving recess 34 at hub 28. See column 3, lines 50-64, and specifically lines 60-64 which state: "During assembly, the collar is passed over the distal end of the hub and forced over distal raised portion 33 so that it snaps into the space between raised portion 32 and raised portion 33 and is trapped in that position." As for flange 40 which was indicated in the Office Action as being an engaging mechanism, note that in fact flange 40 of needle cover 37 has no bearing on the engagement of collar 44, as the only thing that flange 40 does is to expedite the snap fitting of collar 44 to the collar receiving recess 34 of needle hub 28. This is illustrated for example in Fig. 2, where one can see that there is a space at needle hub 28 that is circumscribed by the collar receiving recess 44. See attached Fig. 2 Appendix in which this area is label A. Space A is where the proximal end of needle cover 37, labeled B, fits into, when needle 21 is covered by needle cover or sheath 37. Flange 40, as shown, is chamfered toward the distal end of needle cover 37, so as to facilitate the sliding of collar 44 past needle cover 37, and over flange 40, for snap fitting into the collar receiving recess 34. Indeed, this is disclosed in column 5, lines 47-56 of Gyure which state: "To facilitate this assembly, needle cover 37 includes annular flange 40 which has a tapered outside surface to allow the collar to pass smoothly over annular flange 40 and distal raised portion 33 of the hub and into recess 34 during assembly." At lines 49-53. That cover 37 is connected to the needle hub in the Gyure '295 device, is further evidenced by the disclosure in lines 53-56 of column 5 that needle 21 is being protected by needle cover 37 while the process of fitting collar 44 to collar receiving recess 34 takes place. Moreover, as disclosed in column 4, lines 28-31, Gyure states that the needle cover 37 has "an open proximal end 39 removably engages

hub 28 and covers needle cannula 21, as best illustrated in Fig. 2". Given such unambiguous evidence that his needle cover 37 engages hub 28, and not collar 44 per the explanation given above, it is clear that Gyure does not disclose, or suggest, that his needle cover 37 be engaged to collar 44.

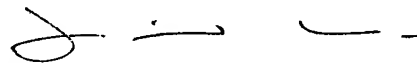
Indeed, none of the other cited references disclose or suggest the connection of a needle protection sheath to a collar that mounts about a needle hub.

Johnson does disclose an adapter that has a housing 42 surrounding an inner luer end 70. However, Johnson, as recognized by the examiner, does not disclose any window at housing 42. This is clear insofar as housing 42 is meant to strengthen the luer end of the syringe to which housing 40 is connected. Thus, to provide an opening to housing 42 would run counter to the adapter as taught by Johnson, since it would tend to weaken it.

Independent claim 11 has been amended to define such window at the ring that surrounds the luer connector.

In light of the foregoing, it is respectfully submitted that all of the pending claims, including objected to claims 6 and 25, are now patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the case to issue at an early date.

Respectfully submitted,



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